K022813

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

August 21, 2002

FEB 1 4 2003

2.1 General Information

2.1.1 Company Name, Address, and Telephone Number

Lake Region Manufacturing, Inc. (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 448-5111 Fax: (952) 448-3441

Contact Name: Karen Mortensen
Regulatory Compliance Specialist

2.1.2 Device Trade Name/Proprietary Name

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

2.1.3 Device Common Names/Usual Names and Classification Names

These devices are commonly known as coronary and peripheral catheter guidewires. The current classification names and product codes are Wire, Guide, Catheter (74DQX).

2.1.4 Establishment Registration Number: 2126666

2.1.5 Classification of Devices

Catheter guidewires have been classified as Class II devices by the Circulatory Systems Devices Panel (reference 21 CFR 870.1330).

2.1.6 Applicability of Performance Standards

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

2.2 Labels, Labeling, and Advertising

LRM produces cardiovascular and vascular guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by

LRM. Changes to the customer controlled labels, labeling, or promotional material are at their discretion, including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

2.3 Statement of Availability

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

2.4 Device Description

2.4.1 Utilizing a proprietary process, LRM produces a PTFE coated stainless steel steerable core. The proximal portion of the core wire is coated with PTFE to provide lubricity and improve wire handling. A platinum alloy coil provides radiopacity in the distal tip. The coil is secured in its location by solder, which is attached to the core. The proximal end of the coil is attached to the core with solder. Additionally, two sections of PTFE are removed from the proximal end of the core to aid in estimating guidewire positioning. The product is offered with a shapeable straight tip or in a preshaped configuration. The guidewires are optionally coated with MDX (silicone). The guidewires are bound by the following parameters:

Outside Diameter:	.018"
Lengths:	130cm – 300cm
Tips:	Straight or shaped with various tip flexibilities
Flexibility:	Floppy to Support

2.4.2 Engineering Specifications

The design specifications are the same for the proposed device as they are for the LRM predicate device [reference 510(k) K970376 and K011968]. The finished devices must meet the same basic design criteria.

2.5 Substantial Equivalence Data

2.5.1 Background Information

The table below lists the differences between the predicate device and the proposed device. Testing was done to ensure the changes to the device met the predetermined performance criteria.

Item	Proposed Device Differences from LRM Predicate cleared under 510(k) K970376 and K011968
Raw Materials	Core: No change Coil: No change Extension system: No change
Assembly Process	No significant change to assembly processes
Physical Characteristics	**No change except to expand the scope of the overall length parameters from: 175cm – 300cm to: 130cm – 300cm** **and to allow radiopaque coil length ranges from 2 cm to 30 cm (was *either* 2 cm *or* 30 cm).**
Labeling/IFU	**The only change to the IFU will be to reference the specific use regarding renal vasculature in addition to the already stated coronary and peripheral vasculature use.**
Intended Use	**No change to intended use except to clarify the guidewire can be used in the renal peripheral vasculature.**
Anatomical Sites	No change
Target Population	No change
Performance Testing	No change
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

2.5.2 In order to demonstrate equivalence of the proposed device, LRM performed testing to established requirements listed in FDA guidance document entitled Coronary and Cerebrovascular Guidewire Guidance, issued January 1995, and ISO 11070 Sterile Single-use Intravascular Catheter Introducers.

2.5.3 Additionally, internal test protocol requirements were utilized to verify the guidewire can be used in the peripheral vasculature, including the renal vasculature.

2.5.4 Configurations, including straight and shaped distal tips were inspected to established criteria. These parts were produced following current manufacturing processes and procedures. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes.

2.6 Qualification and Biocompatibility Test Data

2.6.1 Design Control

LRM is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Risk analysis was completed by means of a Failure Mode and Effect Analysis (FMEA) and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria could be met.

2.6.2 Material/Product/Process Qualification

LRM has formal quality systems in place to assure that the proposed steerable product will remain equivalent to the predicate product, and that the changes will not have an adverse affect on the safe and effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size/group.

2.6.3 Biocompatibility Testing

The materials for the proposed device are identical to the predicate device cleared under K011968 and are identically processed and sterilized. Therefore, biocompatibility testing for the proposed device is not required.

2.7 Packaging and Sterilization Information

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. A portion of the production is private label, sterile packaged to customer specifications, a fraction of that product is provided sterile to the customer.

The single packaged steerable guidewire is placed in a dispenser and then into a Tyvek®/poly pouch. The packaged product may be packaged as five or ten pouchs in a shelf carton, which are typical packaging configurations.

There will be no changes to the sterilization process for the portion of packaged product shipped sterile to the customer. For the product that is shipped bulk, the packaging design and sterilization process parameters are the customer's responsibility. LRM will not recommend that its customers modify their packaging or sterilization procedures as a result of this submission.

2.8 Intended Use Statement

Lake Region's steerable guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature, including the renal vasculature. The steerability feature allows the guidewire to be torqued to facilitate navigation through the vasculature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Lake Region Manufacturing, Inc.
c/o Ms. Karen Mortensen
Regulatory Compliance
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K022813
Trade Name: Coronary Peripheral and Renal Steerable Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II (two)
Product Code: DQX
Dated: December 16, 2002
Received: December 17, 2002

Dear Ms. Mortensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown K022813

Device Name: Steerable Guidewires

Indications for Use:

Lake Region's steerable guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature, including the renal vasculature. The steerability feature allows the guidewire to be torqued to facilitate navigation through the vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ Or Over-The-Counter Use _____
(PER 21 CFR 801.109)

PREMARKET NOTIFICATION

(Division Sign-Off)
9-Division of Cardiovascular Devices

510(k) Number K022813